EXHIBIT BB

CMS Manual System	Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS)
Pub. 100-20 One-Time Notification	
Transmittal 109	Date: August 27, 2004

CHANGE REQUEST 3331

SUBJECT: Billing Instructions for ADVATE rAHF-PFM on Medicare Claims

I. SUMMARY OF CHANGES: This one-time notification informs Medicare contractors to instruct hospitals, providers, and independent ESRD facilities to bill ADVATE rAHF-PFM with HCPCS code J7192.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: July 25, 2003.
                                   IMPLEMENTATION DATE: September 27, 2004

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: N/A
    (R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N/A	

III. FUNDING: Medicare contractors shall implement these instructions within their current operating budgets.

IV. ATTACHMENTS:

	Business Requirements
	Manual Instruction
	Confidential Requirements
X	One-Time Notification
	Recurring Update Notification

*Unless otherwise specified, the effective date is the date of service.

Attachment – One-Time Notification

Pub. 100-20	Transmittal: 109	Date: August 27, 2004	Change Request 3331

SUBJECT: Billing Instructions for ADVATE rAHF-PFM on Medicare Claims

I.   GENERAL INFORMATION

A.   Background:

Advate is a blood-clotting factor that was approved by the U.S. Food and Drug Administration (FDA) on July 25, 2003, for the treatment of hemophilia A.

B.   Policy:

Section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) provides that the payment limits for most drugs and biologicals not paid on a cost or prospective payment basis are based on 85 percent of the Average Wholesale Price (AWP) reflected in the published compendia as of April 1, 2003, for those drugs and biologicals furnished on and after January 1, 2004. However, one of the exceptions to this general rule is the payment limit for blood clotting factors. Specifically, the payment limit for blood clotting factors are 95 percent of the AWP reflected in the published compendia as of September 1, 2003.

Because Advate was approved by the FDA in July 2003, the payment limit that should be used for Advate is the same payment limit that is currently assigned to J7192. For CY 2004, the Advate payment limit for providers and for independent ESRD facilities can be found in the 2004 MMA drug pricing file that was issued in CR 3105 dated January 30, 2004. For hospital OPPS, the payment rate for Advate can be found in the latest quarterly update that is posted on the CMS OPPS Web site.

C.   Provider Education:
A Medlearn Matters provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.

II.   BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
						Shared System Maintainers				Other
		FI	RHHI	Carrier	DMERC	FISS	MCS	VMS	CWF	
3331.1	Contractors shall return to provider (RTP) if the provider bills for Advate using any other code except J7192 (i.e., HCPCS codes J3490, J3590, J7199) effective for dates of service on or after July 25, 2003.	X		X						
3331.2	Contractors shall use the J7192 payment limit for Advate, which was issued in CR 3105, transmittal 75 to this manual, dated January 30, 2004 effective for dates of service on or after January 1, 2004. This payment limit shall apply to all Advate claims submitted from January 1, 2004 through December 31, 2004. The respective quarterly Single Drug Pricer (SDP) payment allowance limit shall apply to all Advate claims submitted between July 25, 2003 through December 31, 2003.	X		X						
3331.3	Contractors shall use the J7192 payment rate for Advate from the latest OPPS OCE quarterly instruction.	X								
3331.4	The payment limit for Advate is to be paid on TOBs 14x, 22x, 23x, 34x, and 72x (for independent facilities only). For TOBs 81x and 82x, hemophilia clotting factors are not separately payable unless condition code 07 is on the claim. Therefore, contractors shall use the J7192 payment limit for Advate only if condition code 07 is present on the claim form.	X		X						
3331.5	Contractors shall not search and adjust claims that have already been processed unless brought to their attention.	X		X						

III.   SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A.   Other Instructions: N/A

X-Ref Requirement #	Instructions

B.   Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C.   Interfaces: N/A

D.   Contractor Financial Reporting /Workload Impact: N/A

E.   Dependencies: N/A

F.   Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: July 25, 2003 **Implementation Date: September 27, 2004** **Pre-Implementation Contact(s):** Marjorie Baldo (marjorie.baldo@cms.hhs.gov) at 410-786-4617 **Post-Implementation Contact(s):** Appropriate Regional Office	Medicare contractors shall implement these instructions within their current operating budgets.

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